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PATENT  
19603/1656 (CRF D-2093C)

RECEIPT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Campbell et al.

Serial No : 09/656,409

Cnfrm No : 9516

Filed : September 6, 2000

For : NON-OCULAR CIRCADIAN CLOCK  
RESETTING IN HUMANS

Examiner:  
Unknown

Art Unit:  
3738

SECOND REQUEST FOR CORRECTED FILING RECEIPT

Assistant Commissioner for Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, D.C. 20231

Dear Sir:

Applicants hereby request a corrected filing receipt for the above-identified application. On the enclosed copy of the official filing receipt, the continuing data is still incorrectly worded. It should read "CONTINUING DATA AS CLAIMED BY APPLICANT - THIS APPLICATION IS A DIV OF 09/074,455 05/07/1998 WHICH CLAIMS BENEFIT OF 60/046,188 05/12/1997 AND 60/072,121 01/22/1998". A copy of page 1 of the Specification as filed indicating the continuing data of the two provisional applications is enclosed herewith.

Since Applicants are not responsible for this error, no fee is enclosed.

Respectfully submitted,

Dated: February 1, 2001

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Certificate of Mailing - 37 CFR 1.8(a)	
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below.	
2/2/2001	<u>Shari A. Moscato</u>
Date	Shari A. Moscato



## NON-OCULAR CIRCADIAN CLOCK RESETTING IN HUMANS

### BACKGROUND OF THE INVENTION

#### 5 1. Field of the Invention

This application claims the benefit of U.S. Provisional Application No. 60/046,188 filed May 12, 1997 and U.S. Provisional Application No. 60/072,121 filed January 22, 1998. This invention was made with Government support under Grant No(s). R01MH45067 and K02MH01099, awarded by the National Institute of Health.

10 The Government has certain rights in the inventions. This invention relates to a method for resetting the phase of the human circadian clock and for enhancing alertness and performance in humans by application of non-solar photic stimulation, in the range of 15 to 150,000 lux, to any non-ocular region of the human body.

#### 15 2. Related Art

As with all vertebrates, humans exhibit temporal organization in behavior and in numerous physiological functions. In response to the natural alternation in light and dark, virtually all species have developed endogenous rhythms with frequencies close to 24 hours. These internally generated, self-sustaining rhythms are known as circadian rhythms (from the Latin *circa* = about, and *dies* = day). The pervasive nature of such rhythms suggests that circadian temporal organization is vital to the overall well-being of the organism. Numerous systems and functions are mediated by the circadian system including hormonal output, body temperature, rest and activity, sleep and wakefulness, and motor and cognitive performance. In all, literally hundreds of circadian rhythms in mammalian species have been identified.

Left to run at its inherent frequency, the human biological clock that is responsible for the generation of circadian rhythms exhibits a daily periodicity of slightly longer than 24 hours. Thus, a daily correction to the clock must be made for our internal rhythms to remain synchronized or 'entrained' to the natural 24 hour day. It is widely accepted that exposure to the natural light/dark cycle provides the strongest signal to entrain the human circadian system to the geophysical day. Inadequate exposure to light of sufficient intensity is a contributing factor in disorders associated with biological rhythm disturbance, such as seasonal affective disorder (SAD), jet lag from transmeridian travel, shift work and some types of insomnia (advanced and delayed sleep phase syndromes).

35 Timed exposure to artificial bright light to the eyes has been used successfully to treat



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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/656,409	09/06/2000	3738	345	19603/1656	7	13	2

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REPLACEMENT FILING RECEIPT



\*OC000000005713813\*

Date Mailed: 01/29/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

**Applicant(s)**

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**Continuing Data as Claimed by Applicant**

THIS APPLICATION IS A DIV OF 09/074,455 05/07/1998 PAT 6,135,117  
~~WHICH AND CLAIMS BENEFIT OF 60/046,188 05/12/1997~~  
~~AND WHICH CLAIMS BENEFIT OF 60/072,121 01/22/1998~~

**Foreign Applications**

If Required, Foreign Filing License Granted 10/20/2000

**\*\* SMALL ENTITY \*\***

**Title**

Non-ocular circadian clock resetting in humans

**Preliminary Class**

128

Data entry by : MEREDITH, WANDA

Team : OIPE

Date: 01/29/2001



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**Title 37, Code of Federal Regulations, 5.11 & 5.15**



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